

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

SARAH PATELLOS and  
ERIC FISHON, on behalf of  
themselves and others  
similarly situated,

Plaintiffs,

vs.

HELLO PRODUCTS, LLC,

Defendant.

CASE NO. 1:19-CV-09577-PAE

**MEMORANDUM OF LAW IN SUPPORT OF**  
**HELLO PRODUCTS, LLC'S MOTION TO DISMISS**

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## **INTRODUCTION**

Plaintiffs Sarah Patellos and Eric Fishon (“Plaintiffs”) bring this putative class action complaint against Defendant Hello Products, LLC (“Hello”), purportedly to challenge statements related to Hello’s activated charcoal toothpaste products. Hello filed a motion to dismiss Plaintiffs’ First Amended Complaint (“FAC”) on June 26, 2020, and instead of opposing that motion, Plaintiffs filed a Second Amended Complaint (“SAC”). But Plaintiffs’ additions are almost all superficial and do not actually include the factual content necessary to cure the deficiencies Hello raised in its prior motion. Accordingly, each cause of action in Plaintiffs’ SAC should still be dismissed, along with Plaintiffs’ challenges in all counts to Hello’s fluoride toothpastes and their request for injunctive relief.

**First**, Plaintiffs’ fraud-based claims are not pled with the particularity required by Federal Rule of Civil Procedure 9(b) or fail to meet the notice pleading standards required by Rule 8(e). **Second**, Plaintiffs’ breach of warranty claims fail because Plaintiffs did not provide the requisite notice and they lack privity with Hello because they purchased through third-party retailers. **Third**, Plaintiffs’ negligent misrepresentation claim is barred by the economic loss rule and, in any event, Plaintiffs did not and cannot allege a special relationship with Hello such that a duty exists. **Fourth**, Plaintiffs’ unjust enrichment claim is improper because Plaintiffs have traditional (albeit meritless) claims available to them. **Fifth**, Plaintiffs’ claims regarding the safety and efficacy of Hello’s fluoride toothpastes are expressly preempted by federal law. **Finally**, Plaintiffs have no standing to seek injunctive relief, as they did not and cannot allege that they would purchase Hello’s products again.

For all of these reasons, and as detailed further below, Hello respectfully moves to dismiss Plaintiffs’ SAC in its entirety.

### **SUMMARY OF ALLEGATIONS AND BACKGROUND**

Hello sells dozens of unique oral care products for babies, children, and adults, including toothpastes, mouthwashes, and toothbrushes. Hello's adult toothpaste products include a line of toothpastes containing activated charcoal, which come in both fluoride and fluoride-free versions. SAC ¶ 3.<sup>1</sup> Hello's Charcoal Toothpastes are among the leading charcoal toothpastes on the market. *Id.* ¶ 5. As reflected by its name, "Hello" is a "naturally friendly™" company, started by a small group of entrepreneurs who were seeking to develop products that utilized thoughtful, responsibly-sourced ingredients, that were never tested on animals, and that employed fun, witty and *honest* labeling. *See generally* <https://www.hello-products.com/>.

Instead of attempting to oppose Hello's June 26, 2020 motion to dismiss Plaintiffs' FAC, Plaintiffs filed their SAC on July 17, 2020. Dkt. 21. Just as they did in their FAC, Plaintiffs list over 30 different product claims in their SAC that Hello allegedly made with respect to its Charcoal Toothpastes, including everything from "slays dragon breath" and "epic whitening" to "a friendly force of nature" and "awesome for fresh breath." *See* SAC ¶¶ 4, 30, 61-71, 75, 77, 86-87, 98, 101, 133. But Plaintiffs do not plainly state which exact claims they seek to challenge in their lawsuit. Hello can only guess whether, for example, Plaintiffs seriously plan to challenge whether the products are, in fact, "awesome" (*id.* ¶ 67) or try to prove that reasonable consumers are confused over whether the products, in fact, slay the breath of dragons (*id.* ¶¶ 66, 68).

While not a model of clarity, the SAC appears to contend generally that Hello is liable to Plaintiffs and a class of other consumers because Hello (1) made various claims regarding its

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<sup>1</sup> Plaintiffs' SAC refers to all of Hello's charcoal toothpastes containing fluoride as the "Fluoride Charcoal Toothpastes," the fluoride free ones as "Fluoride-Free Charcoal Toothpastes" and all of the charcoal toothpastes collectively as "Charcoal Toothpastes." *Id.* ¶ 3. For ease of reference (but not conceding that these toothpastes can be grouped together for all litigation purposes), Hello adopts the same terminology herein.



Charcoal Toothpastes and their “whitening, cleansing, polishing, breath freshening, stain-lifting, plaque-removing, detoxifying, adsorptive” qualities, (2) marketed the Charcoal Toothpastes as “generally safe, effective and beneficial for daily, long term oral care use,” and (3) made statements about its Fluoride Charcoal Toothpaste’s ability to help prevent cavities and strengthen enamel. *Id.* ¶¶ 4, 10, 17, 72–103.

Plaintiff Sarah Patellos resides in New York and alleges that she purchased Hello’s popular fluoride-free toothpaste online on Amazon based on statements she had seen regarding the toothpaste’s ability to naturally whiten her teeth and “that it was safer and less damaging than other whitening toothpastes.” *Id.* ¶ 25. The SAC does not detail Ms. Patellos’s use and experience with Hello’s toothpaste, instead concluding without explanation that Hello’s toothpaste “did not effectively whiten her teeth as expected” and that it “made a big mess.” *Id.* ¶¶ 25-26. There are no allegations regarding exactly what Ms. Patellos expected for Hello’s whitening, or if Ms. Patellos’s expectations align with Hello’s representations. *Id.* Plaintiff Eric Fishon alleges that he purchased at least three types of Hello’s charcoal toothpaste, including both fluoride and fluoride-free versions, from Target online and Amazon. *Id.* ¶ 27. Mr. Fishon allegedly relied on various statements that Hello’s toothpaste had “teeth whitening and detoxifying effects from the activated charcoal, and would promote and benefit oral health, as well as strengthen teeth (as claimed on the fluoride paste).” *Id.* The SAC’s allegations as to Mr. Fishon (as with those relating to Ms. Patellos) conclude without any details or factual support that an unknown Hello toothpaste “did not strengthen his teeth, improve or promote his oral health, or effectively whiten his teeth.” *Id.*

Plaintiffs’ factual allegations about their experiences and Hello’s products end there. The remainder of Plaintiffs’ SAC consists of summaries and out-of-context quotations from various articles regarding charcoal and charcoal pastes, none of which are specific to Hello’s products (*id.*

¶¶ 8, 36–54), summaries of federal regulations (*see id.* ¶¶ 7, 108–116), speculation about Hello’s Charcoal Toothpastes’ lack of the “ADA Seal of Acceptance” (*id.* ¶¶ 9, 55–60, 104, 233),<sup>2</sup> and conclusory statements about Hello’s substantiation, “knowledge,” and consumers’ reliance and injury (*see id.* ¶¶ 7, 8, 10–13, 75, 78, 89, 103, 125–154).

Based on these factually devoid and vague allegations, Plaintiffs claim that Hello is liable to a class of New York consumers for Breach of Express Warranty (Count 1), Breach of the Implied Warranty of Merchantability (Count 2), Deceptive Acts and Practices under New York’s General Business Law § 349 (Count 3), False Advertising under New York’s General Business Law § 350 (Count 4), Negligent Misrepresentation (Count 5), Intentional Misrepresentation/Fraud (Count 6), and Unjust Enrichment (Count 7).

### **ARGUMENT**

To survive a motion to dismiss under Rule 12(b)(6), a complaint must plead “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also* Fed. R. Civ. P. 12(b)(6). A complaint’s “[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint’s allegations are true.” *Twombly*, 550 U.S. at 545. “[T]he doors of discovery” do not unlock “for a plaintiff armed with nothing more than conclusions,” which should be disregarded along with formulaic recitations of elements as well as unwarranted deductions and inferences. *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009); *Twombly*, 550 U.S. at 545. Plaintiffs have not and cannot state claims for relief in any of their seven causes of action, on their fluoride-related product claims, or for any injunctive relief.

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<sup>2</sup> Hello has never claimed that its Charcoal Toothpastes have the ADA Seal of Acceptance, and nowhere in their SAC do Plaintiffs allege Hello has made any such claim. *Id.*

**I. PLAINTIFFS’ FRAUD-BASED CLAIMS ARE NOT PLED WITH THE PARTICULARITY REQUIRED BY RULE 9(b) OR FAIL TO MEET RULE 8(e)’S NOTICE PLEADING STANDARDS (COUNTS 1-7).**

For all claims grounded in fraud,<sup>3</sup> Rule 9(b) “requires that the plaintiff ‘(1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent.’” *Eternity Glob. Master Fund, Ltd. v. Morgan Guar. Tr. Co. of N.Y.*, 375 F.3d 168, 187 (2d Cir. 2004) (quoting *Harsco Corp. v. Segui*, 91 F.3d 337, 347 (2d Cir. 1996)); Fed. R. Civ. P. 9(b). The heightened pleading requirement is designed, in part, to “provid[e] a defendant fair notice of plaintiff’s claim, to enable preparation of defense.” *DiVittorio v. Equidyne Extractive Indus. Inc.*, 822 F.2d 1242, 1247 (2d Cir. 1987). If the Rule 9(b) standard is not met, dismissal under Rule 12(b)(6) is appropriate. *See, e.g., Eternity Glob.*, 375 F.3d at 176–177.

Each of Plaintiffs’ claims is rooted in supposed misrepresentations or omissions regarding Hello’s Charcoal Toothpaste packaging and online presence. Thus, the “gravamen of plaintiffs’ [SAC] is plainly fraud” since they “allege, repeatedly, that [Hello] intentionally made ‘deceptive,’ ‘fraudulent,’ ‘misleading,’ and ‘demonstrably false’ factual representations in labeling and marketing the [] products, [] and purposefully concealed material information about them, [] to induce consumers to rely upon that information and buy and pay premiums for the [] Products.”

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<sup>3</sup> Hello’s Rule 9(b) argument applies to: Count 1 – Alleging that Hello breached an express warranty by misrepresenting that its product had certain characteristics (SAC ¶¶ 166–178); Count 2 – Alleging that Hello breached the implied warranty of merchantability by selling product that was “not in conformance with [Hello’s] representations” (*Id.* ¶¶ 179–186); Count 5 – Alleging that Hello made “many claims it knew were false or misleading” (*Id.* ¶¶ 218–227); Count 6 – Alleging Hello’s acts constituted intentional misrepresentation (*Id.* ¶¶ 228–237); Count 7 – Alleging that “[a]s a result of Hello’s deceptive, fraudulent and misleading labeling, advertising, marketing, and sales” Hello was unjustly enriched (*Id.* ¶¶ 238–243).

*Tyman v. Pfizer, Inc.*, No. 16-CV-06941, 2017 WL 6988936, at \*10 (S.D.N.Y. Dec. 27, 2017). Their allegations must therefore pass Rule 9(b)'s muster.

Plaintiffs' allegations fall far short of Rule 9(b)'s standard. While Plaintiffs added conclusory allegations regarding the products' supposed failures (after Hello moved to dismiss Plaintiffs' FAC), Plaintiffs' allegations are still insufficient to support their fraud-based claims. Instead of alleging supporting *facts* about their experience, which are necessary to allege the "how" of Hello's purported fraud, Plaintiffs merely state unsupported conclusions that Hello's Charcoal Toothpastes "did not effectively whiten" their teeth "as expected," that the product "[was] abrading [Ms. Patellos's] enamel," "did not strengthen [Mr. Fishon's] teeth," and did not "improve or promote his oral health." SAC ¶¶ 25, 27. These conclusory allegations are not facts and provide no *evidentiary* basis for their conclusion that Hello's claims were somehow false. For example: What were Ms. Patellos's "expectations" for Hello's products? How did Ms. Patellos determine that Hello's products were "abrading her enamel"? What facts led Mr. Fishon to claim that Hello's products "did not strengthen his teeth" or "promote his oral health"? Plaintiffs' sweeping, conclusory allegations are not particularized facts sufficient to support fraud-based claims, and thus their claims must be dismissed.

In addition, Plaintiffs' GBL claims (Counts 3 and 4), while not necessarily subject to Rule 9(b)'s heightened pleading requirements (*see Pelman ex rel. Pelman v. McDonald's Corp.*, 396 F.3d 508, 511 (2005)), are nevertheless very much required to meet the "rigorous plausibility standards" set forth in *Iqbal* and *Twombly*. *See Precision Imaging of New York, P.C. v. Allstate Ins. Co.*, 263 F.Supp.3d 471, 476 n.4 (S.D.N.Y. 2017) (noting that "the 'bare-bones notice-pleading requirements' for GBL § 349 claims described in *Pelman* have been superseded by the more rigorous plausibility standards set forth in [*Iqbal* and *Twombly*]"). Like their other fraud-

based claims (*see supra*, n. 3), Plaintiffs’ GBL claims provide no details about which *specific* claims are at issue or were even noticed by Plaintiffs, and no *factual* content (other than “unwarranted deductions and inferences”) that would “allow the court to draw the reasonable inference” that Hello is somehow liable under the GBL for some sort of deception or product misrepresentation. *Iqbal*, 556 U.S. at 678-79. Indeed, Plaintiffs’ SAC includes *over thirty different and varied claims* purportedly from Hello’s product packaging and website. *See, e.g., id.* ¶¶ 4, 30, 61-71, 75, 77, 86-87, 98, 101, 133. And Plaintiffs still fail to allege with any particularity which claim(s) on this laundry list they contend are false and why. Instead, Plaintiffs merely generalize and paraphrase the claims on which they purportedly relied. *Id.* ¶¶ 25, 27.

Because the requisite particular facts are missing from Plaintiffs’ SAC, and because the SAC does not even include a plain statement of which claims Plaintiffs allege they relied on and are fraudulent, Hello is unable to adequately address Plaintiffs’ fraud-based claims and they should be dismissed.

## II. PLAINTIFFS’ BREACH OF WARRANTY CLAIMS FAIL (COUNTS 1 & 2).

In order to state a claim for breach of an express warranty, Plaintiffs must provide timely notice of any breach. *See Hubbard v. Gen. Motors Corp.*, No. 95 CIV. 4362, 1996 WL 274018, at \*5 (S.D.N.Y. May 22, 1996) (dismissing breach of warranty claim because “Plaintiff’s Complaint lacks any allegation that plaintiff notified [the seller] of the claimed defect.”); *Quinn v. Walgreen Co.*, 958 F. Supp. 2d 533, 544 (S.D.N.Y. 2013) (dismissing breach of warranty claims because complaint did not allege that timely notice was provided). Plaintiffs allege that the filing and service of their original complaint constitutes sufficient notice of the breach of warranty claims. SAC ¶ 177. While some courts have permitted a complaint itself to serve as notice (*see Tomasino v. Estee Lauder Companies Inc.*, 44 F. Supp. 3d 251, 262 n.6 (E.D.N.Y. 2014)), such a finding

here would “impede the purposes of the notice requirement.” *See* Notice as condition precedent, 4 Anderson U.C.C. § 2-607:21 (3d. ed.).

Even assuming the original complaint served as notice, it is still insufficient because it is untimely. Mr. Fishon alleges he purchased Hello charcoal toothpastes in February 2019 (SAC ¶ 27), and Ms. Patellos in May 2019 (*id.* ¶ 25). Both Plaintiffs claim that Hello breached its warranty to them when it purportedly failed to whiten their teeth, and, at least for Patellos, it “made a big mess.” *Id.* ¶¶ 25–26. Had this supposed “mess” or inability to “whiten” actually given rise to a breach of warranty claim, such a breach would have been obvious to Plaintiffs shortly after purchasing Hello’s products, and waiting between six and eight months to give Hello “notice” by filing suit is unreasonable as a matter of law. *See In re First Hartford Corp.*, 63 B.R. 479, 487 (Bankr. S.D.N.Y. 1986) (“where . . . there has been a delay of nearly five months before any notification, the buyer had ample opportunity to and did in fact examine the goods, discovering the alleged defect, we hold that notification was untimely”); *Archstone v. Tocci Bldg. Corp. of New Jersey, Inc.*, 959 N.Y.S.2d 497, 499 (2012) (delay in providing notice for goods where “[q]ualities [would have been] apparent, such as size and color, reasonably should be inspected and complained of soon after the goods . . . have been delivered”).

As for Plaintiffs’ claim for breach of implied warranty, Plaintiffs must allege privity of contract in order to state a claim. *Wick v. Wabash Holding Corp.*, 801 F. Supp. 2d 93, 108 (W.D.N.Y. 2011) (“absent any privity of contract between Plaintiff and Defendant, such claim cannot be sustained as a matter of law except to recover for personal injuries.”). Here, Plaintiffs allege that they purchased their products through third-party retailers, Target and Amazon, and thus their breach of implied warranty claim fails. *See* FAC ¶¶ 16–17. In any event, implied warranties do not guarantee that “the product will fulfill a ‘buyer’s every expectation’ but simply

‘provides for a minimum level of quality.’” *See Silva v. Smucker Nat. Foods, Inc.*, No. 14-CV-6154, 2015 WL 5360022, at \*11 (E.D.N.Y. Sept. 14, 2015). Plaintiffs do not allege that their Hello purchases did not provide a “minimum level of quality” for use as a dentifrice, and their implied warranty claims fail on this basis as well.

Thus, Plaintiffs’ breach of warranty claims should be dismissed with prejudice.

### **III. PLAINTIFFS DO NOT AND CANNOT STATE A NEGLIGENT MISREPRESENTATION CLAIM (COUNT 5).**

Under New York law, a negligent misrepresentation claim requires, *inter alia*, that (1) the defendant had a duty, as the result of a special relationship, to give correct information, and (2) the defendant made a false representation that he or she should have known was incorrect. *See Hydro Inv’rs, Inc. v. Trafalgar Power Inc.*, 227 F.3d 8, 21 (2d Cir. 2000). Here, Plaintiffs have not pled any special or “privity-like” relationship with Hello that would give rise to a duty (i.e., that Hello has “unique or specialized expertise” or is “in a position of confidence and trust with the injured party.”). *See Mandarin Trading Ltd. v. Wildenstein*, 16 N.Y.3d 173, 180 (2011). Plaintiffs allege that a special relationship between Hello and Plaintiffs existed because of Hello’s marketing. *See* SAC ¶ 222. But New York courts have consistently rejected that argument. For example, in *Stoltz*, the consumer plaintiffs alleged that a yogurt manufacturer had a special relationship with them because the manufacturer touted the yogurt’s effect on health and had a prominent social media presence that “actively encourage[d] consumers to rely on [the manufacturer’s] reputation and skill in warranting the quality of the products.” *Stoltz v. Fage Dairy Processing Indus., S.A.*, No. 14-CV-3826, 2015 WL 5579872, at \*23 (E.D.N.Y. Sept. 22, 2015). The court rejected the plaintiffs’ contention that advertisements in an arms’-length transaction could form a special relationship. *Id.* at \*25 (citing cases). The court also rejected the plaintiffs’ proposition that the defendants’ “unique expertise as the manufacturer” of the products could form a special relationship. *Id.*; *see also*

*Tyman*, 2017 WL 6988936, at \*16, *report and recommendation adopted*, No. 16-CV-6941, 2018 WL 481890 (S.D.N.Y. Jan. 18, 2018) (rejecting argument that the defendant’s expertise could create a special relationship “where otherwise the relationship between the parties [was] too attenuated”) (quotation omitted). The same result is required here.

Moreover, even if Plaintiffs had adequately alleged the privity-like relationship required to support a negligent misrepresentation claim, their claim still fails because they have only pleaded economic loss (in the form of an unsupported price premium (SAC ¶ 227)), which is insufficient under New York law. *See, e.g., Weisblum v. Prophase Labs, Inc.*, 88 F. Supp. 3d 283, 297 (S.D.N.Y. 2015) (dismissing negligent misrepresentation claim in putative class action where only damages were economic losses); *Gordon v. Hain Celestial Grp., Inc.*, No. 16-CV-6526, 2017 WL 213815, at \*7 (S.D.N.Y. Jan. 18, 2017) (same).

Plaintiffs’ claim for negligent misrepresentation should therefore be dismissed with prejudice.

#### **IV. PLAINTIFFS’ UNJUST ENRICHMENT CLAIM FAILS BECAUSE IT IS DUPLICATIVE OF THEIR OTHER CLAIMS (COUNT 6).**

An unjust enrichment claim is only available in “unusual situations when, though the defendant has not breached a contract nor committed a recognized tort, circumstances create an equitable obligation running from the defendant to the plaintiff.” *Hughes v. Ester C Co.*, 330 F. Supp. 3d 862, 876 (E.D.N.Y. 2018) (granting summary judgment on unjust enrichment claim where the “situation [did not] involv[e] an ‘equitable obligation’ not otherwise recognized by the law”). Here, Plaintiffs’ unjust enrichment claim fails because it merely duplicates their “conventional contract or tort claim[s].” *Id.* at 877. Although many of Plaintiffs’ claims should not survive this motion, unjust enrichment is unavailable as a catchall for allegations that fail to meet the standards required for pleading the claims. *See Corsello v. Verizon New York, Inc.*, 18 N.Y.3d



777, 791 (2012) (dismissing unjust enrichment claim); *Sitt v. Nature's Bounty, Inc.*, No. 15-CV-4199, 2016 WL 5372794, at \*18 (E.D.N.Y. Sept. 26, 2016) (dismissing unjust enrichment claim that overlapped with claims based on GBL §§ 359 and 350). Plaintiffs' unjust enrichment claim should therefore be dismissed with prejudice.<sup>4</sup>

**V. PLAINTIFFS' FLUORIDE-SPECIFIC CLAIMS ARE PREEMPTED (ALL COUNTS).**

Plaintiffs' state law challenges to Hello's claims regarding the safety and efficacy of its fluoride pastes are expressly preempted by federal law and must be dismissed. An otherwise valid state law is preempted if: (1) Congress expressly preempts the state law; (2) Congress completely occupies the law's field of operation; (3) compliance with both federal and state law is impossible; or (4) the state law presents an obstacle to the achievement of the full purposes and objectives of Congress. *See Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 603–07 (1991). Here, Congress has enacted the United States Federal Food Drug, and Cosmetic Act (the "FDCA"), which is a "comprehensive statutory framework for regulating the development and marketing of food, drugs, and cosmetics." *See Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 374 (S.D.N.Y. 2014).

Under the FDCA, fluoride toothpaste is both a drug and cosmetic. *See* SAC ¶ 7. The FDCA expressly preempts state labeling laws that differ from or are not identical to federal law, which prohibits misbranding of both drugs and cosmetics (21 U.S.C. §§ 352(a); 362(a); 21 U.S.C.

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<sup>4</sup> The case Plaintiffs cite to try to support their contention that "[t]his claim is not duplicative" (SAC ¶ 241 n.135), *In re Amla Litig.*, 282 F. Supp. 3d 751 (S.D.N.Y. 2017), has no relevance here. First, that decision is a ruling on a class certification motion, not a motion to dismiss. *Id.* at 757. Second, the Court's analysis of the unjust enrichment claim there addressed whether there were privity or reliance requirements, but did not evaluate the propriety of the claim in light of other available remedies as the courts did in Hello's cited cases.

§§ 379r(a), 379s(a)). The FDA has exclusive regulatory authority over enforcement. *See Bowling*, 65 F. Supp. 3d at 374.

Fluoride toothpastes are expressly regulated by the FDA through the issuance of a final monograph. A “monograph” is a federal regulation that “sets out the FDA-approved active ingredients for a given therapeutic class of [over-the-counter] drugs and provides the conditions under which each active ingredient is [generally recognized as safe and effective].” *Natural Res. Def. Council, Inc. v. FDA*, 710 F.3d 71, 75 (2d Cir. 2013). Where an applicable monograph exists, manufacturers do not need to obtain individual FDA approval and may market products in accordance with the monograph, including labeling requirements. *Id.*

The FDA has published a monograph in the Code of Federal Regulations that governs “Anticaries Drug Products,”<sup>5</sup> including toothpaste. *See* 21 C.F.R. § 355.1. The monograph states that “[a]n over-the-counter anticaries drug product in a form suitable for topical administration to the teeth is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.” *Id.* The monograph also makes clear that toothpastes that contain fluoride **must** state on the packaging that fluoride “[a]ids in the prevention of dental (select one of the following: ‘cavities,’ ‘decay,’ ‘caries (decay),’ or ‘caries (cavities)’).” *See* 21 C.F.R. § 355.50(b). And the monograph permits fluoride products to use variations of that claim on its labeling. *Id.* “In other words, pursuant to the 1995 Monograph, manufacturers of OTC drugs containing sodium fluoride are allowed (1) to represent that such drugs prevent tooth decay and (2) to provide further labeling to explain how decay is prevented.” *Bowling*, 65 F. Supp. 3d at 373.

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<sup>5</sup> Defined as “[a] drug that aids in the prevention and prophylactic treatment of dental cavities (decay, caries).” 21 U.S.C. § 355.3(c).

As Judge Scheindlin explained in a similar case:

[P]reemption is certainly appropriate when a state law prohibits labeling that is permitted under federal law. But it is *also* appropriate when a state law prohibits labeling that is *not prohibited* under federal law. The standard, in other words, is not whether a state law actively undermines federal law. It is whether state law diverges from federal law *at all* . . . . For plaintiffs to establish that their state law claims are not preempted, it is insufficient to show that the FDA has not permitted the label ‘Restores Enamel.’ Rather, plaintiffs would need to plead facts suggesting that the FDA has affirmatively *prohibited* the label. Otherwise, plaintiffs’ state law causes of action would be, in effect, imposing a labeling requirement that is ‘not identical with’ labeling requirements under federal law.

*Id.* at 375-76 (emphasis in original). Here, as in *Bowling*, Plaintiffs contend that the state laws of New York prohibit Hello from making claims about the efficacy and safety of fluoride when used in Hello’s fluoride toothpaste. *See* SAC ¶¶ 67, 69, 87, 96–98. But the FDA’s regulations already cover fluoride toothpaste, and expressly permit Hello to make the claims it does. *See* 21 C.F.R. § 355.50(b); *Bowling*, 65 F. Supp. 3d at 375. Thus, this application of state law is expressly preempted by the FDCA and the applicable regulations. Plaintiffs even recognize as much. *See* SAC ¶¶ 104–108. Thus, Plaintiffs cannot state any cause of action challenging Hello’s claims regarding fluoride safety and efficacy.<sup>6</sup>

## **VI. PLAINTIFFS LACK STANDING TO SEEK INJUNCTIVE RELIEF.**

When seeking prospective injunctive relief, a plaintiff must prove the likelihood of future or continuing harm. *City of Los Angeles v. Lyons*, 461 U.S. 95, 111 (1983); *Berni v. Barilla S.p.A.*, 964 F.3d 141, 147 (2d Cir. 2020). Plaintiffs cannot make this showing where their allegations instead show they are “unlikely to purchase [the challenged] products again.” *Hidalgo v. Johnson & Johnson Consumer Companies, Inc.*, 148 F. Supp. 3d 285, 291 (S.D.N.Y. 2015); *Deshawn E. by Charlotte E. v. Safir*, 156 F.3d 340, 344 (2d Cir. 1998) (plaintiff “must show a likelihood that he

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<sup>6</sup> *See, e.g.*, SAC ¶¶ 3–4, 40, 51–52, 28, 67, 69, 96–98.

or she will be injured in the future” to claim injunctive relief); *Reid v. GMC Skin Care USA, Inc.*, No. 8:15-CV-277, 2016 WL 403497, at \*7 (N.D.N.Y. Jan. 15, 2016) (“[A] plaintiff who has not alleged that she will purchase the offending product in the future has not established the likelihood of future injury required by Supreme Court and Second Circuit precedent.”).

Here, Plaintiffs cannot seek injunctive relief because they do not plead any intention to purchase the product again, and Plaintiffs’ allegations that they would not have purchased a product but for defendant’s misrepresentation is “effectively a concession that [plaintiff] does not intend to purchase the product in the future.” *Duran v. Henkel of Am., Inc.*, No. 19 CIV. 2794, 2020 WL 1503456, at \*12 (S.D.N.Y. Mar. 30, 2020) (Engelmayer, J.) (dismissing injunctive relief claims where plaintiff in consumer class action alleged that he would not have purchased the product with the claims made at the price stated). Plaintiffs’ request for injunctive relief must therefore be stricken. SAC at VII.(b)-(c); *see also Berni*, 964 F.3d at 149 (finding that classwide “injunctive relief is not proper for . . . past purchasers” and rejecting cases holding otherwise).<sup>7</sup>

Further, even if Plaintiffs had standing to request injunctive relief (they do not), injunctive relief is not available in this case because monetary damages are sufficient to remedy any purported injuries. An injunction is an “extraordinary remedy” available only where remedies available at law, such as monetary damages, are inadequate to compensate for an irreparable injury. *eBay, Inc. v. MercExchange L.L.C.*, 547 U.S. 388, 391 (2006). Thus, injunctive relief is not appropriate

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<sup>7</sup> Plaintiffs cannot rely on *In re Amla Litig.* to save their request for injunctive relief (*see* SAC ¶ 34 n.12) because the Second Circuit’s recent *Berni* decision expressly rejected the reasoning in *In re Amla Litig.* *See Berni*, 964 F.3d at 148 & n.30 (“We are aware that some district courts in this [c]ircuit have been hesitant to find that past purchasers cannot obtain injunctive relief . . . [b]ut such an equitable exception to Rule 23(b)(2) simply does not exist, and courts cannot create one to achieve a policy objective . . .”) (expressly overruling *In re Amla Litig.*).

where, as here, Plaintiffs claim monetary damages would provide adequate compensation. *Jayaraj v. Scappini*, 66 F.3d 36, 39 (2d Cir. 1995).

Thus, Plaintiffs' claims for injunctive relief should be dismissed.<sup>8</sup>

### **CONCLUSION**

Because Plaintiffs' SAC fails to state claims for which relief may be granted, Hello respectfully requests that the Court dismiss each and all of Counts 1-7 with prejudice. Hello also requests that the Court dismiss with prejudice Plaintiffs' claims regarding the safety and efficacy of Hello's Fluoride Charcoal Toothpastes for enamel and preventing cavities, and Plaintiffs' request for injunctive relief.

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<sup>8</sup> Certain courts have elected to analyze motions directed at a requested remedy or form of relief under Rule 12(f) rather than Rule 12(b)(6). *See, e.g., Marshall v. New York State Pub. High Sch. Athletic Ass'n, Inc.*, 290 F. Supp. 3d 187, 204 (W.D.N.Y. 2017) (finding motion directed to the third prayer for relief as "more properly deemed a motion to strike" and treating it as such); *but see Wray v. Edward Blank Assocs., Inc.*, 924 F. Supp. 498, 501 (S.D.N.Y. 1996) ("Technically, motions to strike are not proper methods of disposing of part or all of a complaint."). Hello's motion meets the standard under either rule. *See* Fed. R. Civ. P. 12(f) (permitting a court to strike from a pleading any redundant, immaterial, or impertinent matter). Here, Plaintiffs' SAC seeks relief that is barred as a matter of law. Permitting the request for injunctive relief to remain in Plaintiffs' SAC will force Hello and the court to waste time dealing with forward-looking issues and discovery and potentially a meritless Rule 23(b)(2) class certification motion.

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Respectfully submitted,  
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